Clinical trial results:
Placebo-controlled double-blind trial investigating the efficacy and tolerability of Posterisan® akut with lidocaine 60 mg/suppository in abatement of complaints associated with hemorrhoids

Summary

EudraCT number	2012-002083-27
Trial protocol	DE
Global end of trial date	27 August 2013

Results information

Result version number	v1 (current)
This version publication date	01 June 2016
First version publication date	05 August 2015
Summary attachment (see zip file)	Synopsis KAD 169 (Synopsis_KAD169.pdf)

Trial information

Trial identification

Sponsor protocol code	KAD169

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Dr. Kade Pharmazeutische Fabrik GmbH
Sponsor organisation address	Rigistraße 2, Berlin, Germany, 12277
Public contact	Medical department, Dr. Kade Pharmazeutische Fabrik GmbH, 0049 3072082330, medizin@kade.de
Scientific contact	Medical department, Dr. Kade Pharmazeutische Fabrik GmbH, 0049 3072082330, medizin@kade.de

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	27 August 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 August 2013
Global end of trial reached?	Yes
Global end of trial date	27 August 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Proof of superior efficacy of Posterisan® akut mit Lidocain 60 mg/Zäpfchen compared with placebo (vehicle without active substance) in the relief of symptoms associated with hemorrhoids

Protection of trial subjects:

No specific measures

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 November 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 203
Worldwide total number of subjects	203
EEA total number of subjects	203

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	149
From 65 to 84 years	52
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited at study centers in Germany from November 2012 to August 2013.

Pre-assignment

Screening details:

Screening due to the inclusion and exclusion criteria, no special information

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Monitor, Subject

Blinding implementation details:

identical packaging and labelling of the two compounds

Arms

Are arms mutually exclusive?	Yes
Arm title	Posterisan akut

Arm description:

Treatment with lidocaine containing suppositories for 3 days

Arm type	Experimental
Investigational medicinal product name	Posterisan® akut mit Lidocain 60mg/ Zäpfchen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suppository
Routes of administration	Rectal use

Dosage and administration details:

2-3 times per day (single dose: 60 mg lidocaine) for a total treatment duration of 3 days

Arm title	Placebo

Arm description:

Treatment with Placebo suppositories for 3 days

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suppository
Routes of administration	Rectal use

Dosage and administration details:

2-3 times per day (single dose: 60 mg lidocaine) for a total treatment duration of 3 days.

Number of subjects in period 1	Posterisan akut	Placebo
Started	102	101
Completed	102	101

Baseline characteristics

Reporting groups	
Reporting group title	Posterisan akut
Reporting group description:	
Treatment with lidocaine containing suppositories for 3 days	
Reporting group title	Placebo
Reporting group description:	
Treatment with Placebo suppositories for 3 days	

Reporting group values	Posterisan akut	Placebo	Total
Number of subjects	102	101	203
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	78	69	147
From 65-84 years	24	30	54
85 years and over	0	2	2
Gender categorical Units: Subjects			
Female	49	57	106
Male	53	44	97
Most bothersome symptom			
Most bothersome symptom (ie pain, burning or itching) is defined as the most annoying haemorrhoidal symptom at Baseline.			
Units: mmVAS			
arithmetic mean	77.6	78.9	
standard deviation	± 9.6	± 9.6	-

Subject analysis sets	
Subject analysis set title	ITT population
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Any subject who applied the trial medication at least once.	
Subject analysis set title	PP population
Subject analysis set type	Per protocol
Subject analysis set description:	
All ITT subjects who have concluded the trial in conformance with the trial protocol (i. e. without major protocol violation).	

Reporting group values	ITT population	PP population	
Number of subjects	203	173	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	147	146	
From 65-84 years	54	25	
85 years and over	2	2	
Gender categorical Units: Subjects			
Female	106	89	
Male	97	84	
Most bothersome symptom			
Most bothersome symptom (ie pain, burning or itching) is defined as the most annoying haemorrhoidal symptom at Baseline.			
Units: mmVAS			
arithmetic mean	78.2	78.8	
standard deviation	± 9.6	± 9.4	

End points

End points reporting groups

Reporting group title	Posterisan akut
Reporting group description:	
Treatment with lidocaine containing suppositories for 3 days	
Reporting group title	Placebo
Reporting group description:	
Treatment with Placebo suppositories for 3 days	
Subject analysis set title	ITT population
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
Any subject who applied the trial medication at least once.	
Subject analysis set title	PP population
Subject analysis set type	Per protocol
Subject analysis set description:	
All ITT subjects who have concluded the trial in conformance with the trial protocol (i. e. without major protocol violation).	

Primary: Improvement from Baseline in the most bothersome symptom at Day 3

End point title	Improvement from Baseline in the most bothersome symptom at Day 3[1]
End point description:	
Improvement from Baseline in the most bothersome symptom at the day of treatment completion (Day 3)	
End point type	Primary
End point timeframe:	
3 days	
Notes:	
[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point. Justification: See attached synopsis	

End point values	Posterisan akut	Placebo	ITT population	PP population
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	102	101	203	173
Units: mmVAS				
arithmetic mean (standard deviation)	33.3 (± 24.1)	32.9 (± 25.7)	33.1 (± 24.9)	33.7 (± 23.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Improvement from Baseline in MBS at treatment Day 1

End point title	Improvement from Baseline in MBS at treatment Day 1
End point description:	
Improvement from Baseline in MBS at treatment Days 1 and 2	
End point type	Secondary

End point timeframe:

1 day

End point values	Posterisan akut	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	102	101		
Units: mmVAS				
arithmetic mean (standard deviation)	17.8 (± 23.8)	16.8 (± 19.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Between-group comparison of MBS responder rates at Day 3

End point title	Between-group comparison of MBS responder rates at Day 3

End point description:

Between-group comparison of MBS responder rates (response defined as an absolute value ≤30 mmVAS) at the day of treatment completion (Day 3).

End point type	Secondary

End point timeframe:

3 days

End point values	Posterisan akut	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	102	101		
Units: number subjects	31	28		

Statistical analyses

No statistical analyses for this end point

Secondary: Improvement from Baseline in MBS at treatment Days 2

End point title	Improvement from Baseline in MBS at treatment Days 2

End point description:

End point type	Secondary

End point timeframe:

2 days

End point values	Posterisan akut	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	102	101		
Units: mmVAS				
arithmetic mean (standard deviation)	25 (± 22.1)	25.4 (± 21.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean changes in burning from baseline to Day 4

End point title	Mean changes in burning from baseline to Day 4

End point description:

End point type	Secondary

End point timeframe:

4 days

End point values	Posterisan akut	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	102	101		
Units: mmVAS				
arithmetic mean (standard deviation)	26.6 (± 28)	29.5 (± 26.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean changes in itching from baseline to Day 4

End point title	Mean changes in itching from baseline to Day 4

End point description:

End point type	Secondary

End point timeframe:

4 days

End point values	Posterisan akut	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	102	101		
Units: mmVAS				
arithmetic mean (standard deviation)	32.4 (± 28.8)	34.8 (± 30.1)		

Statistical analyses

No statistical analyses for this end point

Post-hoc: Mean changes in pain from Baseline to Day 4

End point title	Mean changes in pain from Baseline to Day 4

End point description:

Mean changes in pain from Baseline (Day 0) to final study assessment (Day 4)

End point type	Post-hoc

End point timeframe:

4 days

End point values	Posterisan akut	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	102	101		
Units: mmVAS				
arithmetic mean (standard deviation)	19.9 (± 32.3)	21.5 (± 29.5)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Day 0 to Day 4	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	14
Reporting groups	
Reporting group title	Posterisan akut
Reporting group description: Subjects who administered Posterisan akut	
Reporting group title	Placebo
Reporting group description: Subjects who administered placebo	

Serious adverse events	Posterisan akut	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Infections and infestations			
Anal abscess			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Posterisan akut	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	11 / 102 (10.78%)	10 / 101 (9.90%)	
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 102 (0.98%)	1 / 101 (0.99%)	
occurrences (all)	1	1	
Dysgeusia			

subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	
occurrences (all)	1	0	
Headache			
subjects affected / exposed	1 / 102 (0.98%)	1 / 101 (0.99%)	
occurrences (all)	1	1	
General disorders and administration site conditions			
Anal fissure			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	
occurrences (all)	1	0	
Chills			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	
occurrences (all)	1	0	
Fatigue			
subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	4 / 102 (3.92%)	2 / 101 (1.98%)	
occurrences (all)	4	2	
Abdominal pain			
subjects affected / exposed	2 / 102 (1.96%)	1 / 101 (0.99%)	
occurrences (all)	2	1	
Anorectal discomfort			
subjects affected / exposed	1 / 102 (0.98%)	3 / 101 (2.97%)	
occurrences (all)	1	3	
Defaecation urgency			
subjects affected / exposed	1 / 102 (0.98%)	1 / 101 (0.99%)	
occurrences (all)	1	1	
Diarrhoea			
subjects affected / exposed	3 / 102 (2.94%)	3 / 101 (2.97%)	
occurrences (all)	3	3	
Flatulence			
subjects affected / exposed	1 / 102 (0.98%)	1 / 101 (0.99%)	
occurrences (all)	1	1	
Nausea			

subjects affected / exposed	1 / 102 (0.98%)	0 / 101 (0.00%)	
occurrences (all)	1	0	
Rectal discharge			
subjects affected / exposed	1 / 102 (0.98%)	1 / 101 (0.99%)	
occurrences (all)	1	1	
Rectal haemorrhage			
subjects affected / exposed	0 / 102 (0.00%)	1 / 101 (0.99%)	
occurrences (all)	0	1	
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	1 / 102 (0.98%)	1 / 101 (0.99%)	
occurrences (all)	1	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 April 2013	Addition of study centers

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported